

Draft, 3/00

SDMS Document ID



2006963

Exposure Investigation Protocol
Vasquez Boulevard and I-70 Site
March, 2000
DRAFT

Consistency of
DATA for Phase
Bonne III.

TINERONE —

These handouts are from
the 3/21 Health Team
meeting.

Michael

9:00am —
HHS Conf. Call
for coordination

U.S. Department of Health and Human Services
Agency for Toxic Substances and Disease Registry

Draft, 3/00

Objective

Recent soil sampling results for the Vasquez Boulevard and I-70 (VBI70) site have shown elevated arsenic levels in surface soil samples from residential yards in the area. In some areas, arsenic soil levels have exceeded 1000 mg/kg. To evaluate whether excess arsenic exposure is occurring among residents, the Agency for Toxic Substances and Disease Registry (ATSDR) will test urine and hair samples from individuals living at residences with the highest measured soil arsenic levels.

Results of this investigation will be used to identify appropriate follow-up health activities in this community. As a public health investigation rather than research study, these results are applicable only to this site and are not generalizable to other sites or populations.

Background

The VBI70 site is located in the northern section of Denver. The site is bounded on the west by the South Platte River, on the east by Colorado Boulevard, on the north by East 52nd Avenue, and on the south by Martin Luther King Boulevard. Within this area are two historic smelters with a current smelter located nearby. In July 1997, the Colorado Department of Public Health and Environment (CDPHE) collected 25 soil samples from residential yards in the Elyria and Swansea neighborhoods. Arsenic levels ranged from 12-1300 mg/kg. To further characterize the extent of contamination, USEPA collected several thousand soil samples from approximately 1500 properties in the area during Phase I and II field investigations in the spring and summer of 1998. Twenty-one properties had an arsenic soil concentration from composite samples of the front and back yard of greater than 450 mg/kg and/or lead soil concentration greater than 2000 mg/kg and were identified for a time-critical removal action. Eighteen of these underwent remediation (USEPA, 1998, USEPA, 1999).

In November 1998, USEPA conducted limited biomonitoring of residents at properties with the highest arsenic and/or lead concentrations. Biological samples consisting of a blood lead, urinary arsenic, and hair arsenic were obtained from 15 volunteers who were living at six of the 21 residences identified for the removal action. Ages ranged from three to 85 years with 13 of 15 participants nine years of age or older. Blood lead measurements were all less than 5 µg/dL. Arsenic was not detected in any urine samples (reporting limit 20 µg/L) and was detected in only one hair sample at a level of 0.41 µg/g. Lead or arsenic were not considered elevated in any of the samples. Retesting of urine samples was considered due to some dilute samples which affected the detection limits but none of the participants chose to accept this offer. USEPA noted that while the data did not suggest exposure levels to lead and arsenic were significantly greater than normal, interpretation was limited due to the small number of participants.

In 1999, soil samples were obtained from approximately 3000 additional properties by USEPA during Phase III sampling activities. Preliminary results have indicated that 23 properties have average soil arsenic concentrations of 400 mg/kg or greater and two properties have average soil lead concentrations greater than 2000 mg/kg. These properties are currently being considered for

Draft, 3/00

a removal action anticipated to begin in April 2000. USEPA has provided vouchers to residents at these highest contaminated properties to obtain urine arsenic, hair arsenic, and blood lead testing at a nearby clinic. A number of other properties have been identified with elevated soil arsenic levels which may be remediated at a later date.

In order to further define potential arsenic exposure, ATSDR proposes to test additional volunteers from the residences with highest soil arsenic. The rationale for an exposure investigation is to collect biological data from a select sample of individuals in order to assess actual exposures that may be occurring rather than relying solely on risk assessment methods or models of exposure. The investigation is not intended to provide comprehensive screening for an entire community nor is this type of screening within the resources of ATSDR. Typically, an exposure investigation will attempt to sample those considered to have the highest risk of potential exposure to a chemical to assess the magnitude of exposure and need for additional studies or follow-up. By testing those individuals with the highest potential for exposure, results can be used in directing further investigations, if indicated.

Arsenic Biomonitoring Methods

Arsenic can be measured in urine, hair, or blood to evaluate exposure. A limitation of these tests is that they can only evaluate relatively recent exposures to arsenic. There are no methods currently available to measure arsenic exposures which have occurred more than a few months prior to testing. Of these tests, urine arsenic is the best method for measuring arsenic exposure and can measure exposures occurring within a few days of the specimen collection. Although a 24-hour urine collection is considered optimal due to fluctuations in excretion rates, most exposure studies have used a first morning void or random sample due to ease of collection. Under steady state exposure conditions, as would be assumed for most residents of this community, random or spot urine results have correlated well with 24-hour results. Speciated urinary arsenic is preferable to total urinary arsenic since the speciated forms can distinguish between exposure to inorganic arsenic and its metabolites and the relatively non-toxic forms of organic arsenic commonly found in seafood. Because this investigation is concerned with possible exposure to arsenic in residential soil, urine sampling ideally should occur during periods in the year in which there is no snow cover and individuals are likely to be spending time outdoors.

Measurement of arsenic in hair can be used to evaluate potential exposures occurring during the time of hair growth, since a small amount is incorporated into the hair as it grows. Theoretically, this could determine exposures occurring over several months depending on the length of the hair. However, external arsenic such as dust particles, can adsorb strongly to the hair surface and is not easily washed off even by laboratory methods. Thus, it is difficult to distinguish whether arsenic measured in hair samples is the result of internal absorption or toxicologically insignificant deposition of dust on the hair surface. In addition, reference levels for arsenic in hair have not been well-established which further complicates interpretation (ATSDR, 1998; Lauwerys and Hoet, 1993; National Research Council, 1999). While the toxicologic significance of hair arsenic may be difficult to determine, increased hair arsenic values may be of some value in demonstrating increased contact with arsenic in the environment.

Draft, 3/00

Measurement of arsenic in blood is not a reliable indicator of chronic exposure to low levels of arsenic since it is cleared from the blood within a few hours and reflects only very recent exposure. Blood arsenic levels are also difficult to interpret since the relationship between levels of exposure and blood concentrations has not been well-established.

Agency Roles

ATSDR will be the lead agency in this investigation and will prepare a final report describing the investigation and results. ATSDR will work closely with USEPA, CDPHE, and the community and solicit their input at each stage of the investigation.

Methods

Target Population

The target population for the investigation is primarily preschool children living at properties with the highest soil arsenic concentrations based on USEPA Phase III sampling results. Young children are generally assumed to be at most risk of exposure to chemicals in soil due to their increased soil contact and tendency to ingest soil either intentionally or through normal "mouthing" behavior. Based on interests and concerns expressed by the community, the investigation will also include a small number of other individuals who may have an increased potential for exposure such as adults living at properties with high soil arsenic, gardeners, or children who do not live at one of the properties with high soil arsenic concentrations but may frequently play in an area with high soil arsenic.

The number of participants in the investigation will be limited to approximately 100. As discussed in conference calls with the community, the investigation will attempt to enroll a sample composed of the following:

Draft, 3/00

- ab70 preschool children (i.e., 2-6 years of age) either living at a property with high arsenic soil concentrations or who may frequently play at properties with high arsenic soil concentrations
- ab20 adults living at a property with high arsenic soil concentrations
- ab10 adults who garden and live at a property with high arsenic soil concentrations

Draft, 3/00

Residences will be listed in descending order of mean arsenic surface soil concentrations. From this list, residences with the highest arsenic soil concentrations will initially be contacted by ATSDR to determine if they wish to participate. Participation will be voluntary. Should residents either not wish to participate or not fit inclusion criteria, residences lower on the list will be considered for possible inclusion in the investigation until a sample of approximately 100 with the above distribution is achieved. Individuals in which it would be difficult to obtain a urine sample, such as very young children, or individuals living at a property which has undergone soil remediation will not be considered eligible for testing. The investigation will include participants from the Phase III properties initially identified by USEPA for remediation, provided their property has not undergone remediation at the time of testing and they have not previously been tested using vouchers provided by the USEPA.

Biological Sampling

Participants will be instructed to not eat fish, shellfish, or other seafood for approximately five days prior to testing as this may affect results. Participants will be asked to report to a central location (to be identified). Testing procedures will be explained to each participant. Each participant will be required to sign an informed consent form prior to participation (Attachment A). For participants less than 18 years of age, a parent or legal guardian will be required to sign the consent form. Following completion of the consent forms, a hair sample will be collected by investigation staff according to testing laboratory protocol (Attachment B). When possible, hair will be collected from the back of the head/neck area. A bundle of hair approximately 1/4 inch in diameter will be collected and placed in a laboratory-supplied container.

At this time, participants also will receive necessary supplies and instructions (Attachment C) for collecting a first morning void urine sample at their home. While a first morning void is considered optimal, it is recognized that for some individuals such as young children, this may not always be possible. In such cases, a urine sample (i.e., random sample) collected at some other point during the day can be substituted. Participants will be instructed to return the urine sample the following day.

ATSDR will attempt to accomodate those individuals who are unable to travel to the central collection point by either providing transportation or possibly collecting the specimens at their home.

Appropriate chain-of-custody procedures will be observed for all specimens (i.e., specimens will be sealed in the presence of the participant and initialed by the participant). Once sealed, specimens will be shipped via overnight delivery to the contract laboratory, National Medical Services, Inc. (NMS), for analysis. Samples will be tested for total inorganic arsenic which includes inorganic species (As(III) and As(V)), and the metabolites methylarsonic acid (MMA), and dimethylarsinic acid (DMA). The laboratory detection limit for total inorganic analyses is approximately 10 µg/L. The reference standard cited by NMS for total inorganic arsenic in unexposed populations is less than 20 µg/L and will be used as a comparison value. Urine will also be tested for specific gravity and creatinine to evaluate urine concentration and determine creatinine-adjusted arsenic concentrations.

Draft, 3/00

Hair samples will be washed by the NMS according to their standard protocols. Samples will be tested using graphite furnace atomic absorption spectroscopy with a detection limit of approximately 0.3 mcg/g. NMS reports a reference range of 0.03-3 mcg/g.

Urinary and hair arsenic concentrations will be compared to reference ranges and also stratified by age and residential soil arsenic concentrations to identify possible correlations.

Reporting of Results

ATSDR will mail individual test results as they become available to the participants and will provide an explanation of their significance. Confidentiality will be protected according to Federal and State laws. Summary data for the investigation may be reported in public documents. However, summary data will not include any personal identifiers such as specific addresses or names. Individual test results will not be made available to the public.

Follow-up Activities

ATSDR will prepare a written report which discusses the investigation findings. This report will be available to the general public, health and environmental agencies, and other concerned parties. The report will not contain any personal identifiers. The report will contain recommendations based on urinary arsenic sampling results.

ATSDR is unable to provide medical treatment or advice. In the event significantly elevated urinary arsenic concentrations are found, the individual will be notified and assistance provided in terms of determining potential exposure pathways and methods of reducing exposure.

Results of the investigation will serve as a basis for follow-up health activities. This may include community health education, health care provider education, or additional biological sampling.

References

Agency for Toxic Substances and Disease Registry (ATSDR). Toxicological Profile for Arsenic (Update). US Department of Health and Human Services, August, 1998.

Lauwerys RR, Hoet P. Industrial Chemical Exposure. Guidelines for Biological Monitoring. 2nd Ed. Boca Raton: Lewis Publishers, 1993.

National Research Council. Arsenic in Drinking Water. Washington, DC: National Academy Press, 1999.

United States Environmental Protection Agency (USEPA). Project Plan for the Vasquez Boulevard I-70 Site, Denver, CO. Phase III Field Investigation. Denver: USEPA, August 4, 1999.

United States Environmental Protection Agency (USEPA). Sampling Analysis Report - Phase II Sampling for Removal Site Assessment. Vasquez Boulevard/Interstate 70 Site, Denver, CO.

Denver:USEPA, September 21, 1998.ATTACHMENT A

ATTACHMENT A

Consent Form for Participation VB-I70 Exposure Investigation

The Agency for Toxic Substances and Disease Registry (ATSDR) is conducting an investigation of possible exposure to inorganic arsenic among selected residents of the VB-I70 site in Denver, CO, who reside at properties with increased soil arsenic levels. A urine sample will be collected from participants and tested for inorganic arsenic, methylarsonic acid (MMA), and dimethylarsinic acid (DMA). Specific gravity and creatinine, which are routine measures of urine concentration, will also be determined. A hair sample also will be collected and tested for total arsenic. Your participation will help to determine if increased exposure to inorganic arsenic is occurring.

Procedure

Instructions and a collection kit for obtaining a urine sample in the privacy of your home will be provided. A hair sample approximately the diameter of a pencil will be collected from the back of the head area. In addition to testing, basic identifying information will be collected for each participant such as name, age, and address.

Participation

Participation in this investigation is voluntary. Even if I agree to participate and sign this form, I can stop my participation or my child's/ward's participation at any time without any consequences. I understand and agree that there is no provision for compensation or medical treatment by ATSDR or other environmental and health agencies based on test results. I understand that I must sign this form to participate.

Confidentiality

Confidentiality will be protected in accordance with State and Federal laws. Individual test results will not be made available to the public, but may be shared with other federal, state, or local health or environmental agencies if authorized by me. Grouped data analyses or reports may be generated as a result of this investigation but will not include any information that may identify individuals.

Results

ATSDR will provide you with your individual test results and an explanation of their significance. I understand that if my results reveal an elevated value of arsenic, I will be contacted about providing additional information to better determine sources of exposure and ways to minimize exposure in the future.

Consent

I have read the description of this exposure investigation. All of my questions have been satisfactorily answered. I voluntarily request that I be included in this investigation.

Name (print): _____

Signature: _____

Address: _____

Phone: _____

Age: _____

Date: _____

Witness (print): _____

Witness (signature): _____

My test results may be shared with other Federal, state, or local public health or environmental agencies.

Signature: _____

Draft, 3/00

The Agency for Toxic Substances and Disease Registry (ATSDR) is conducting an investigation of possible exposure to inorganic arsenic among selected residents of the VB-I70 site in Denver, CO, who reside at properties with increased soil arsenic levels. A urine sample will be collected from participants and tested for inorganic arsenic, methylarsonic acid (MMA), and dimethylarsinic acid (DMA). Specific gravity and creatinine, which are routine measures of urine concentration, will also be determined. A hair sample also will be collected and tested for total arsenic. Your participation will help to determine if increased exposure to inorganic arsenic is occurring.

Procedure

Instructions and a collection kit for obtaining a urine sample in the privacy of your home will be provided. A hair sample approximately the diameter of a pencil will be collected from the back of the head area. In addition to testing, basic identifying information will be collected for each participant such as name, age, and address.

Participation

Participation in this investigation is voluntary. Even if I agree to participate and sign this form, I can stop my participation or my child's/ward's participation at any time without any consequences. I understand and agree that there is no provision for compensation or medical treatment by ATSDR or other environmental and health agencies based on test results. I understand that I must sign this form to participate.

Confidentiality

Confidentiality will be protected in accordance with State and Federal laws. Individual test results will not be made available to the public, but may be shared with other federal, state, or local health or environmental agencies if authorized by me. Grouped data analyses or reports may be generated as a result of this investigation but will not include any information that may identify individuals.

Results

ATSDR will provide you with your individual test results and an explanation of their significance. I understand that if my results reveal an elevated value of arsenic, I will be contacted about providing additional information to better determine sources of exposure and ways to minimize exposure in the future.

**Assent Form for Children
(7-17 years old)**

This statement is to be read to children in the presence of the parent/guardian:

"We want to find out if you have been exposed to arsenic which may be found in the soil of some areas in your neighborhood. Arsenic is something you can not see and may affect your health. To see if you have arsenic in your body, we would like to take a sample of your urine. The urine sample can be collected when you first wake up in the morning by placing a small amount in a test cup when you first go to the bathroom. It is considered very safe and your (mother/father/guardian) has said that it would be all right for you to do this."

"Do you have any questions? May we take the samples that your (mother/father/guardian) agreed to?"

The above information has been read to me, and I want to participate.

Name of Child: _____ Age: _____

Signature of Child: _____

Name of Parent or Legal Guardian: _____

Signature Parent/Guardian: _____ Date: _____

Child's Home Address: _____

Telephone number: _____

Witness (print): _____

Witness (signature): _____

Test results may be shared with other Federal, state, or local public health or environmental agencies

Signature of parent/guardian : _____

ATTACHMENT B
VB-I70 Exposure Investigation - Hair Collection Protocol

When possible, hair specimens will be collected from the back of the head. Collection methods will differ slightly depending on the length of hair. Steps for hair collection as outlined by the testing laboratory are described below.

To collect hair at least 2 inches long:

Step 1: The person collecting the donor's hair should wash their hands thoroughly with soap and water.

Step 2: Remove the alcohol wipe packet and the white capped bottle labeled Hair Collection Container from the resealable plastic bag. This bottle contains the hair collection tube, which has been split down its length.

Step 3: Find an appropriate spot on the back of the head for hair collection. The metal clip may be useful to partition the hair from the hair to be tested. Tightly twist a bundle of hair, making sure that it is approximately 1/4 inch in diameter.

Step 4: While holding the tightly twisted bundle of hair in one hand, spread open the hair collection tube with the other hand, then enclose the hair bundle with this tube as close to the donor's scalp as possible. The twisted hair bundle should be thick enough to completely fill the hair collection tube.

Step 5: Clean the scissor blades with the alcohol wipe. Cut the twisted hair bundle as close to the scalp as possible. Use extreme care not to injure the donor. Do not remove the collection tube from the cut hair. Tie twist tie tightly around the root end.

Step 6: Place the hair with the collection tube and twist tie in the Hair Collection Container provided and label.

Step 7: Place Hair Collection Container with the donor's hair back into the plastic bag and reseal it.

To collect hair samples less than 2 inches long:

Step 1: The person collecting the donor's hair should wash their hands thoroughly with soap and water.

Step 2: Remove the alcohol wipe packet and the small hair collection vial.

Step 3: Clean scissor blades with the alcohol wipe. Using extreme care not to injure the donor, cut hair as close to the scalp as possible. Place the cut hairs in the small screw capped vial provided. Attempt to fill this vial with loosely packed hairs.

Step 4: Seal the small vial, label, and place in the plastic bag and reseal.

ATTACHMENT C
VB-I70 Exposure Investigation - Urine Collection Instructions

Urine Collection Kits

Each person submitting a urine sample will be supplied with a sample kit in a resealable plastic bag. The kit will contain:

- a plastic cup for collecting urine
- a plastic bottle with lid which will be used to send the urine sample to the laboratory. The bottle will be labelled with your name and an identifying number when you receive it.
- absorbent material

Urine Collection Instructions

- The urine sample should be collected from the first morning urination after waking up. If this is not possible, the sample can be collected at some other time during the day.
- We suggest placing the plastic bag containing the urine collection supplies in your bathroom the night before collection. Do not open the bag until you are ready to collect the urine sample.
- Be sure to wash your hands with soap and water before urinating. Rinse hands well and dry with a clean towel.
- Do not open the plastic bottle until you are ready to collect your sample. When you unscrew the lid from the plastic bottle, place it top-side down (i.e., rim up) on a clean surface. Handle the lid by the outer edges only. Do not touch the part of the lid that may come in contact with urine after it is resealed.
- The urine sample can be collected by urinating into the plastic bottle or into the supplied plastic cup. If using the cup, immediately transfer the contents of the cup to the plastic bottle. With either method, fill the plastic bottle 1/4 to 1/2 full. The plastic cup can be thrown away once you have transferred the contents to the plastic bottle. Do not use the plastic cup for more than one sample collection.
- Screw the bottle cap on tightly immediately after collection and wipe any excess urine from the outside of the bottle with a clean paper towel.
- Place the bottle in the plastic zip-lock bag and reseal. Place the bag in a safe location until you are ready to return it. You do not need to refrigerate your urine sample.
- When you return the plastic bottle, we will seal it with custody tape which you will be required to initial. The plastic bottle will be sent by overnight mail to the testing laboratory. The laboratory will not test the specimen if the custody tape is not present or is broken.